DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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Evidence Based Assisted Reproductive Technologies (ART); Public Workshop

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AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

The Food and Drug Administration (FDA) in cosponsorship with the National Institutes of Health (NIH), and Department of Health and Human Services (DHHS), Office of Women's Health is announcing the following public workshop entitled: "Evidence Based Assisted Reproductive Technologies (ART)." The topics to be discussed include: (1) The FDA regulatory framework; (2) methods of supporting research in this area by NIH; and (3) scientific, social, ethical and policy issues concerning ART.

Date and Time: The public workshop will be held on September 18, 2002, from 8:30 a.m. to 4:30 p.m., and September 19, 2002, from 8 a.m. to 12 a.m.

Location: The public workshop will be held at Lister Hill Center, Bldg. 38A, NIH, 8600 Rockville Pike, Bethesda, MD.

Contact Person: *For information about this notice*: Michael D. Anderson, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–6210, FAX 301–594–1944.

For information about the public workshop: Melanie Whelan, Center for Biologics Evaluation and Research (HFM–40), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–3079, FAX 301–827–3843, or e-mail: whelan@cber.fda.gov.

Registration: Send registration information (including name, title, firm name, address, telephone, and fax number) to Melanie Whelan (see *Contact Person*) by Friday, September 6, 2002. The registration form is available at http://www.fda.gov/cber/meetings.htm. There is no

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registration fee for the public workshop. Space is limited, therefore interested parties are encouraged to register early. There will be no onsite registration.

If you need special accommodations due to a disability, please contact Melanie Whelan at least 7 days in advance.

SUPPLEMENTARY INFORMATION: This public workshop will provide a forum for discussion of scientific, social, ethical, and policy issues related to ART. The public workshop will be of primary interest to consumers, researchers, academia, ART practitioners, and sponsors of clinical trials evaluating novel ART. The goals of the public workshop are to: (1) Assess the usefulness of animal models in evaluating the safety and efficacy of human ART, and (2) identify social and ethical issues specific to ART. These issues are of interest to FDA, NIH, and DHHS to guide development of scientific initiatives, policy, and regulations in this area and to identify areas where research funding may be needed.

Transcripts: Transcripts of the public workshop may be requested in writing from the Freedom of Information Office (HFI–35), Food and Drug Administration, 5600 Fishers Lane, rm. 12A–16, Rockville, MD 20857, approximately 15 working days after the meeting at a cost of 10 cents

per page. The transcript of the workshop will also be available on the Internet at http://www.fda.gov/cber/minutes/workshop-min.htm.

Dated: 7/8/02
July 8, 2002.

Margaret M. Dotzel,
Associate Commissioner for Policy.

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